

ADVIA 1200, 1650, 1800 and 2400 Chemistry Systems

Ratio Parameters Flagging Behavior for All Software Versions

Our records indicate that you are using an ADVIA® 1200, 1650, 1800, or 2400 Chemistry System.

Reason for Field Correction

Siemens Healthcare Diagnostics is conducting a field correction for ADVIA 1200, 1650, 1800 and 2400 Chemistry Systems.

Siemens has confirmed that the ADVIA Chemistry Systems above will report results calculated using the Ratio Parameters feature without error flags when underlying individual test results used as part of the calculation are flagged. In cases where an error flag suppresses a numerical result, a ratio calculation will not be performed. If a numerical result is generated with a flag, the ratio will be reported without a flag.

Risk to Health

Individual test results associated with common ratio tests (ex. Anion Gap, A/G ratio, Osmolality, and estimated ionized calcium) have clinical utility, and are typically reviewed and reported in conjunction with the ratio. However, the %HbA1c_3 method may be set up to report only the Ratio Parameters result, in which case a ratio value with a flagged component value may be reported without appropriate review or retest, potentially leading to inappropriate assessment of a patients' level of glycemic control.

Based on a Siemens internal risk analysis, a lookback at previous results is not recommended. Please review this letter with your laboratory Medical Director.

Siemens Healthcare Diagnostics

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

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Actions to be Taken by the Customer

1. Identify Ratio Parameters tests on your system and their individual component assays.

Use your site Tech Manager/Supervisor Password for your account to enter System Setup. In System Setup select **Ratio Parameters** to review your Ratio Parameters setup screen. Identify which Ratio Parameters assays are set up on your system and the individual assays that make up the Ratio Parameters tests. These tests should be reviewed before approving Ratio Parameters assay results. Common Ratio Parameters calculated assays include: %HbA1c, Anion Gap, A/G ratio, Osmolality, and Ionized Calcium. This is not an all inclusive list. Every site has the ability to create User Defined methods that use the Ratio Parameters feature to set up any individual assay to be part of a calculated result of their design.

2. Review and evaluate Flags/Marks associated with individual component assays before reporting Ratio Parameters assay results.

Review Options:

- a. Review all results from the ADVIA Chemistry System Review and Edit screen before reporting Ratio Parameters results.
- b. Work with your CentralLink™ specialist to determine an optimized workflow solution. The CentralLink system can hold flagged individual test results and the resulting calculated assay result for your review and approval.
- c. If you do not have a CentralLink system, please work with your LIS/middleware provider to ensure that individual component assays of a Ratio Parameters test are being reviewed before the Ratio Parameters calculated result is approved.

3. For technical questions, contact your local Siemens Healthcare Diagnostics Technical Solutions Support Team:

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry Systems Ratio Parameters Flagging Behavior for All Software Versions

CHSW 13-01

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated September 2013 regarding ADVIA Chemistry Systems Ratio Parameters Flagging Behavior for All Software Versions (10814864 Rev. A). Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page within 30 days of receipt.

1. I have read and understood the Urgent Field Safety Notice instructions provided in the September 2013 letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. I have identified the Ratio Parameters tests and/or individual component assays, and our site will implement a workflow to review all component and ratio results before reporting Ratio Parameters results.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Name of person completing questionnaire: Block Capitals	Date:	
	Phone No:	

Title:		Instrument Serial Number:	
Hospital:		Street:	
City:		Post Code:	
Email:		Signed:	

PLEASE FAX OR EMAIL THIS COMPLETED FORM TO:

FAX 0845 605 6800

EMAIL: robert.davies@siemens.com

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